UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,596	06/27/2003	Leszek Wojnowski	VOS-14 CON	4858

1473 7590 03/26/2007

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1211 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-8704

EXAMINER	
GREENE, JAIME M	
ART UNIT	**PAPER NUMBER**
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,596	WOJNOWSKI ET AL.	
	Examiner	Art Unit	
	Jaime M. Greene	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 17, 18, 36, 37, 44, drawn to a polynucleotide, classified in class 536, subclass 23.1.

II. Claim 9, drawn to a method of making a molecular variant of a CYP3A5 polypeptide using host cells, classified in class 435, subclass 70.1.

III. Claim 10, drawn to making host cells expressing a molecular variant of a CYP3A5 polypeptide, classified in class 435, subclass 455.

IV. Claims 11, 17, 18, 36, 37, 44, drawn to a polypeptide, classified in class 530, subclass 300.

V. Claims 12-14, 17, 18, 36, 37, 44, drawn to an antibody, classified in class 530, subclass 387.1.

VI. Claims 15-16, 44, drawn to a transgenic animal, classified in class 800, subclass 8.

VII. Claim 19, drawn to a method of identifying a polymorphism, classified in class 435, subclass 6.

VIII. Claims 20-28, drawn to a method of identifying a pro-drug, classified in class 435, subclass 4.

IX. Claims 29-35, drawn to a method of diagnosing a disorder, classified in class 436, subclass 2.

X. Claims 38-43, drawn to a method of preparing a composition, classified in class 435, subclass 91.1.

Note: See restriction of subinventions below

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the host cell of invention I can be used in a materially different process, for example for as a means to amplify the cloned sequence.

3. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of invention I could be used simply as a means to amplify the cloned polynucleotide rather than to express a molecular variant of the CYP3A5 polypeptide as required by invention III.

4. The inventions I, IV and V are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the

inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs, functions, and effects because they are drawn to products having different structures and functions. The polynucleotide of invention I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The protein of invention 4 and the antibody of invention V are both composed of amino acids linked by peptide bonds, however antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of inventions I, IV and V can be used in materially different processes, for example the polynucleotde of invention I can be used to transform bacteria, the polypeptide of invention IV can be used to examine protein:protein binding interactions, and the antibody of invention V can be used in immunoassays. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of inventions I, IV and V are patentably distinct from each other. The search for each of inventions I, IV and V presents a serious search burden as the searches for each are not coextensive in scope. The inventions have different status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to antibodies, which would not have described the

polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the antibody but spoke to the gene. Searching, therefore is not coextensive. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. The Inventions I and VI are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs, that of invention I being a polynucleotide and that of invention VI being an entire organism. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6. Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of invention I can be used as a probe for a Southern blot.

7. Inventions I, IV, V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products of inventions I, 1V, and V can be used in materially different processes, such as examining intramolecular binding forces.

8. Inventions I, IV, V, and IX are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, inventions I, IV, and V are not made by the process of invention IX, because, as disclosed, the method seeks to determine the presence of the already-present inventions, and therefore is not a process of making said inventions.

9. Inventions I, IV, V, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, inventions I, IV, and V can be used in materially different processes, including as probes for Southern blots (invention I), .

10. Inventions II and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the

inventions as claimed have materially different effect, that of invention II being the recovery of a protein and that of invention III being the production of a genetically engineered cell. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

11. Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of invention IV can also be made by *in vitro* translation.

12. Inventions II and V are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the cells engineered by the process of invention II are not designed to encode nor can they make the antibody of invention V.

13. Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have materially different designs, that of invention I being a method for recovering a protein from a cultured cell and that of invention VI being a transgenic animal. Also the

transgenic animal cannot be cultured, as required by invention II, and therefore cannot be used for the process of invention II.

14. Inventions II and VII are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different modes of operation and effects. Specifically, invention II involves the culturing of cells for the purpose of recovering a protein whereas invention VII involves comparing polynucleotide sequences. Also, the buffers and reagents needed for these methods are different, because polynucleotides and polypeptides are molecules with distinct structures and functions requiring handling conditions that favor the molecular properties of each. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

15. Inventions II and VIII are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different effects, that of inventions II being the recovery of a polypeptide and that of invention VIII being the identification of a prodrug

that interacts with said polypeptide. The inventions also have materially different designs, invention II requiring cell culture which is not required for invention VIII. The solutions and conditions required to culture cells are distinct from those needed to assess drug activity. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

16. Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the diagnostic method of invention IX is not disclosed as capable of use together with the recombinant protein production method of invention II; the methods differ in design, mode of operation, and effect because invention IX is designed to produce information about a possible genetic defect in a subject by detecting a specific polynucleotide, while invention II is designed to produce a polypeptide using a genetically engineered a host cell.

17. Inventions II and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of preparing a diagnostic composition of invention X is not disclosed as capable of use together with the method of isolating a polypeptide of invention II. The methods differ in design, mode of operation, and effect because invention X is designed to diagnose a disease whereas invention II is designed to produce a polypeptide.

18. Inventions III and IV are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the polypeptide of invention IV cannot be used in the process producing genetically engineered cells of invention III because polypeptides cannot be used to genetically engineer cells, as is known in the art.

19. Inventions III and V are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody of invention V cannot used in the process of invention III because antibodies cannot be used to genetically engineer cells, as is known in the art.

20. Inventions III and VI are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the transgenic animal of invention VI cannot be made by the process of invention III because invention III is the process of producing a genetically engineered genetically engineered cells alone do not produce transgenic animals.

21. Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions have different designs, modes of operation, and effects because the method

of invention VII is designed to identify a polymorphism by examining a polynucleotide and the method of invention III is produce genetically engineered cells.

22. Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions have different designs, modes of operation, and effects because invention VIII is designed to identify a prodrug whereas invention III is designed to produce genetically engineered cells.

23. Inventions III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the inventions have different designs, modes of operation, and effects because invention IX is designed to produce information about a possible genetic defect in a subject by detecting a specific polynucleotide whereas invention III is designed to produce genetically engineered cells.

24. Inventions III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, and effects because invention X is designed to prepare a diagnostic composition whereas invention III is designed to produce genetically engineered cells.

25. Inventions IV and VI are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs, that of invention VI being a transgenic animal and that of invention IV being a polypeptide. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

26. Inventions IV and VII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the polypeptide of invention IV cannot be made by the process of invention VII because invention VII is designed to identify a polymorphism of a nucleic acid sequence, which in no way involves polypeptides.

27. Inventions V and VI are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs, that of invention VI being a transgenic animal and that of invention V being a antibody. Furthermore, the inventions

as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

28. Inventions V and VII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody of invention V cannot be made by the process of invention VII because invention VII is designed to identify a polymorphism of a nucleic acid sequence, which in no way involves antibodies.

29. Inventions VI and VII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the transgenic animal of invention VI cannot be used in the method of identifying a polymorphism, because the method is used to identify said polymorphism in a population in which the polynucleotide sequence in the subjects is unknown, and in the case of the transgenic animal, the polymorphism was engineered into the animal and is already known.

30. Inventions VI and VIII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the transgenic animal of invention VI cannot be used in the method of identifying a prodrug of invention VIII, because the method is uses already isolated molecules and additional steps would be required to obtain the molecules used in the method from said animal.

31. Inventions VI and IX are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the transgenic animal of invention VI cannot be used in the method of identifying a molecular variant, because the method is uses already isolated molecules and additional steps would be required to obtain said molecules used in the method from said transgenic animal.

32. Inventions VI and X are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the transgenic animal of invention VI cannot be used in the method of preparing a diagnostic composition, because the method is uses already isolated molecules and additional steps would be required to obtain said molecules used in the method from said transgenic animal.

33. Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions VII and VIII are not disclosed as capable of use together and they have different designs, modes of operation, and effects, namely invention VIII is designed to identifying a prodrug and has distinct steps and a distinct outcome from that of invention VII, which is designed to identify a polymorphism in a nucleic acid sequence.

34. Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions VII and IX are not disclosed as capable of use together and they have different designs, modes of operation, and effects, namely invention IX is designed to diagnose a disorder and has distinct steps and a distinct outcome from that of invention VII, which is designed to identify a polymorphism.

35. Inventions VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions VII and IX are not disclosed as capable of use together and they have different designs, modes of operation, and effects, namely invention X is designed to prepare a diagnostic composition using an already-isolated polynucleotide and has distinct steps and a distinct outcome from that of invention VII, which is designed to identify a polymorphism in a method that includes isolating a polynucleotide, said step not included in the method of invention X.

36. Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions VII and IX are not disclosed as capable of use together and they have different designs, modes of operation, and effects, namely invention IX is designed to

diagnose a disorder and has distinct steps and a distinct outcome from that of invention VIII, which is designed to identifying a prodrug.

37. Inventions VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions VII and IX are not disclosed as capable of use together and they have different designs, modes of operation, and effects, namely invention X is designed to prepare a diagnostic composition and has distinct steps and a distinct outcome from that of invention VIII, which is designed to identifying a prodrug.

38. Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions VII and IX are not disclosed as capable of use together and they have different designs, modes of operation, and effects, namely invention X is designed to prepare a diagnostic composition and has distinct steps and a distinct outcome from that of invention IX, which is designed to diagnose a disorder.

Election/Restrictions Subinventions

39. Additionally, each invention named above is subject to further restriction. For each of the following claims, applicant is required to elect a single patentably distinct invention to which the claims will be limited.

For each of the inventions I-X above, applicant is required to elect one of the following polynucleotide sequences:

1) one specific polynucleotide sequence from subpart a, or

2) one specific nucleotide sequence from subpart b, or

3) one polynucleotide sequence from subpart c including a specific position to be modified along with the modification to be made (e.g. a deletion, an addition or one of the substitutions) identified in subpart d of the claim, or

4) one specific nucleotide sequence from subpart e including a specific position to be modified along with the modification to be made (e.g. a deletion, an addition or one of the substitutions), or

5) one specific nucleotide sequence from subpart f including the specific position to be modified along with the specific amino acid modification to be made (e.g. a an amino acid substitution of S to Y at a position corresponding to position 100 of the CYP3A5 polypeptide).

For invention I above,

Applicant is required to elect one of the following, identified in claim 3: DNA or RNA.

Applicant is required to elect one of the following, identified in claim 7: prokaryotic cells, eukaryotic cells, isolated fractions of prokaryotic cells, or isolated fractions of eukaryotic cells.

For invention VI above, applicant is required to elect one of the following, identified in claim 16: mouse, rat or zebrafish

For inventions I, IV and V above, applicant is required to elect one of the following, identified in claim 18: a membrane, a glass chip, a polypropylene chip, a silicon chip, oligonucleotide conjugated beads, or an oligonucleotide conjugated bead array.

For invention VIII above, applicant is required to elect one of the following, identified in claim 20, step (a): the polypeptide, the solid support, the cell expressing a molecular variant gene, the gene, or the vector.

For inventions IX and X above,

Applicant is required to elect one of the following, identified in claim 32 and 43:

cancer, cardiovascular disease, diabetes, or AIDS.

For invention IX above,

Applicant is required to elect one of the following, identified in claim 33: PCR, ligase chain reaction, restriction digestion, direct sequencing, nucleic acid amplification techniques, hybridization techniques, mass spectroscopy, or immunoassay.

The subinventions identified above are directed to related products or processes. The related products have different molecular structures with materially different designs,

functions, and effects. The related processes also have materially different designs (including by requiring distinct pieces of equipment) functions, and effects,

This is NOT an election of species. The variants in claims 1,3, 7, 16, 18, 32, 33, 40, and 43 are not considered to recite a proper genus/Markush group. Each of these variants are structurally and/or functionally distinct. Given the difference in structure and/or function, the Markush groups set forth in claims 1-3, 7, 16, 18, 32, 33, 40, and 43 are not consider a proper genus and therefore are subject to further requirement. A sequence search and non-patent literature search of these variants would not be co-extensive with one another. These variants are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such variants is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). Searching more than one of the claimed patentably distinct sequences represents a serious burden to the office.

40. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jaime M. Greene whose telephone number is 571-270-3052. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZACHARIAH LUCAS
PATENT EXAMINER

JMG 3/8/07